

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF MISSOURI  
EASTERN DIVISION

<b>MARIANNE PRATHER</b>	)
	)
	)
<b>Plaintiff,</b>	)
	)
v.	) <b>Case No. 4:08-cv-558</b>
	)
<b>ORGANON USA, INC,</b>	)
<b>ORGANON PHARMACEUTICALS USA, INC,</b>	)
<b>and ORGANON INTERNATIONAL, INC, and</b>	)
<b>MERCK &amp; CO., INC</b>	)
	) <b>JURY TRIAL DEMANDED</b>
<b>Defendants.</b>	)
	)
	)

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**This document relates to 4:08-md-01964-RWS *In Re: Nuvaring Products Liability Litigation***

**AMENDED COMPLAINT**

COMES NOW Plaintiff Marianne Prather (hereinafter “Plaintiff”), by and through undersigned counsel, pursuant this Court’s Scheduling Order for Phase I Potential Bellwether Trial Pool Cases, and for her Amended Complaint against Organon USA, Inc., Organon Pharmaceuticals USA, Inc., and Organon International, Inc., and Merck & Co., Inc., states as follows:

**PARTIES AND JURISDICTION**

1. Plaintiff is a resident of the State of Missouri.
2. Defendant Organon International, Inc. is a Delaware for-profit corporation with its principal place of business at 56 Livingston Ave., Roseland, New Jersey 07068.

Defendant Organon International, Inc. is a subsidiary of Dutch Chemicals Defendant Akzo Nobel. At all times relevant, Defendant Organon International, Inc. was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, the prescription drug, NuvaRing.

3. Defendant Organon USA, Inc. is a New Jersey corporation with its principal place of business at 56 Livingston Ave., Roseland, New Jersey 07068. Defendant Organon USA, Inc. is a sales unit of the healthcare group of Defendant Akzo Nobel NV and Defendant Organon International, Inc. At all times relevant, Defendant Organon USA, Inc. was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, the prescription drug, NuvaRing.

4. Defendant Organon Pharmaceuticals USA, Inc. is a Delaware corporation with its principal place of business at 56 Livingston Ave., Roseland, New Jersey 07068. Organon Pharmaceuticals, Inc. is the United States pharmaceutical arm of Defendant Organon International, Inc. At all times relevant, Defendant Organon Pharmaceuticals USA, Inc. was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, the prescription drug, NuvaRing.

5. Schering Plough Corporation (herein after “Schering-Plough”) is a New Jersey corporation organized, existing and conducting business in the State of New

Jersey. Schering Plough acquired Organon BioSciences NV (OBS), in November 2007 and assumed the liabilities attendant thereto, including the liabilities of Defendant Organon USA, Inc. Organon BioSciences, NV, is comprised of Organon, a human health business (which includes Organon USA, Inc.), Intervet, an animal health business, Nobilon, a human vaccine development unit, and Diosynth, a third party manufacturing arm of Organon.

6. In 2008, Schering Plough acquired Organon Pharmaceuticals USA, Inc., and caused it to be dissolved as a corporation; and made it a subsidiary. In so doing, Schering Plough assumed the liabilities of Organon Pharmaceuticals USA, Inc. Upon information and belief, Organon Pharmaceuticals, Inc. was the United States pharmaceutical arm of Defendant Organon International, Inc. Until dissolution Organon Pharmaceuticals USA, Inc. was engaged in the business of designing, licensing, manufacturing, distributing, packaging, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, the prescription drug, NuvaRing®. Upon information and belief, Organon Pharmaceuticals USA, Inc. was at all times relevant to this Complaint part of the Akzo Nobel, NV business unit of Organon.

7. Schering-Plough expressly and/or impliedly assumed the liabilities and obligations of Defendants Organon USA, Inc. and Organon International, Inc., including the injuries and damages associated with NuvaRing and alleged herein.

8. Hereinafter, Defendants Organon International, Inc., Organon USA, Inc., and Organon Pharmaceuticals USA, Inc., will be referred to collectively as “Organon.” At all times material, Defendants Organon designed, innovated, marketed,

manufactured, sold, and labeled a product known as the NuvaRing, containing both an estrogen and progestin hormone, intended for intimate body use.

9. In or about November 2009, Defendant Merck & Co., Inc., (herein after "Defendant Merck"), a New Jersey corporation organized, existing and conducting business in the State of New Jersey with its principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033, completed the acquisition and merger with Schering-Plough Corporation and upon further information and belief expressly and/or impliedly assumed the liabilities of both Schering-Plough and the named Organon defendants for the injuries and damages alleged herein resulting from Plaintiff's use of NuvaRing. Therefore, Defendant Merck is liable as a successor in interest and/or successor corporation for the liabilities and obligations of Schering-Plough and Defendant Organon as alleged by Plaintiff.

10. This court has personal jurisdiction over the defendants in that the prescription drug at issue, NuvaRing, was prescribed to, marketed, and sold to Plaintiff in the State of Missouri.

11. This court has subject-matter jurisdiction over this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between the parties and the amount in controversy exceeds \$75,000.00 exclusive of interest and costs.

12. Venue in this district is appropriate under 28 U.S.C. § 1391 because a substantial part of the events giving rise to this claim occurred in this district, as Plaintiff was prescribed and used NuvaRing in this district, Plaintiff suffered injury in this district, and because Plaintiff at all times relevant resided in this district. Furthermore,

the Defendants collectively have marketed, sold, distributed or otherwise distributed NuvaRing within the Eastern District of Missouri.

### **FACTUAL BACKGROUND**

13. Upon information and belief, upon the acquisition by Defendant Merck of Defendant Organon, Defendant Merck assumed the liabilities and obligations of Defendant Organon associated with NuvaRing®, including the liabilities associated with the damages and injuries alleged herein by Plaintiff. Therefore, all named Defendants are liable to Plaintiff who was injured due to her use of the said NuvaRing product, either by virtue of being the corporation which engages in the conduct stated in paragraph 8, or as successor corporations having assumed the liability through the purchase of a predecessor corporation.

14. Defendants Organon market NuvaRing as the first and only, once-a-month vaginal birth control ring, and further markets NuvaRing as providing the same efficacy as birth control pills or the patch in preventing pregnancy, but with more convenience because it offers “month-long protection against pregnancy, so women who use NuvaRing don't have to think about contraception every day.”

15. At all times material hereto, Defendants Organon failed to properly disclose the known safety hazards associated with NuvaRing.

16. The package insert accompanying NuvaRing stated that the vaginal ring is expected to be associated with similar risks to that of birth control pills and that the safety information they provide to consumers is derived primarily from studies of birth control pills.

17. Therefore, the safety information provided to the consumer was not derived primarily from studies of NuvaRing and, therefore, the package insert accompanying NuvaRing is misleading.

18. Defendants Organon failed to warn of the extent of the risk of venous thromboembolism, including Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE), and death associated with use of the novel combined contraceptive vaginal route of administration, the NuvaRing.

19. Etonogestrel, a synthetic, third-generation progestin, that Defendants Organon use in the NuvaRing as a starting agent, was not the subject of sufficient and adequate testing, and Defendants Organon knew or should have known that information conveying potential adverse events involving DVT, PE, and death should be set forth in the package insert.

20. Defendants knew, but failed to disclose that the NuvaRing had a higher risk of thromboembolic complications than the pill, due to the markedly potentiated androgenic effects caused by the synthetic, third-generation progestin used in the NuvaRing.

21. Defendants Organon negligently and/or recklessly marketed the NuvaRing as a novel vaginal delivery system, and placed the product into the stream of commerce without conducting adequate tests to regulate the exposure and/or release rates of estrogen and Progestin to a user, including Plaintiff, of such product.

22. At all times material hereto, Defendants Organon, by and through their agents, servants and/or employees, negligently, recklessly, carelessly and/or grossly

negligently marketed, distributed and/or sold NuvaRing without adequate instructions or warnings of its known serious side effects and unreasonably dangerous risks.

23. Instead, Defendants Organon market NuvaRing as having a low risk of side effects and continues to minimize NuvaRing's side effects by focusing on the incidence of minor side effects, stating, "With NuvaRing there is a low incidence of side effects, such as headaches, nausea, and breast tenderness."

24. As a result of the claims of Defendants Organon regarding the effectiveness and safety of NuvaRing, Plaintiff began using the NuvaRing contraceptive in or about August 2003. While on the NuvaRing, on October 4, 2003, at age 33, Plaintiff experienced severe shortness of breath, as well as pain while breathing and coughing.

25. As a result of her sharp pain and trouble breathing, in the early morning of October 5, 2003, Plaintiff was admitted into St. Joseph Health Center, at which time she was still using the NuvaRing. During the course of her examination, Plaintiff was instructed to immediately remove the NuvaRing.

26. A CT scan of Plaintiff's chest revealed a significant pulmonary embolus in her right lung. Plaintiff was immediately placed on anticoagulation therapy, including Coumadin and Heparin, and was told to discontinue the use of NuvaRing. Plaintiff was hospitalized for four days. On October 8, 2003, Plaintiff was discharged from the hospital with instructions to remain on Coumadin therapy indefinitely.

27. As a direct and proximate result of using the NuvaRing, Plaintiff suffered injuries and continues with regular follow-up care.

28. Prior to Plaintiff's use of NuvaRing, Defendants Organon knew or should have known that use of their products created a higher risk of venous thromboembolism and death than oral contraceptives.

29. Despite the fact that Defendants Organon knew or should have known of the serious health risks, including venous thromboembolism and death associated with the use of the NuvaRing particularly to Plaintiff, Defendants failed to warn Plaintiff of said serious risks before she used the product and failed to conduct appropriate testing prior to the NuvaRing being prescribed to Plaintiff.

30. Had Plaintiff known the risks and dangers associated with NuvaRing, she would not have used NuvaRing and would not have suffered the aforementioned injuries.

31. As a direct and proximate result of Plaintiff's use of NuvaRing, Plaintiff suffered intense and excruciating physical pain and suffering from the initial onset of her injuries until she ultimately required hospitalization, including but not limited to the fact that she was unable to breathe during that time.

32. Further, as a direct and proximate result of Plaintiff's use of NuvaRing, Plaintiff has suffered economic and non-economic losses, has incurred hospital expenses and because Plaintiff must remain on anticoagulation therapy for the remainder of her life, she is having difficulty finding life insurance.

33. Defendants Organon's actions and omissions as identified in this Complaint demonstrate a flagrant disregard for human life, so as to warrant the imposition of damages based on aggravating circumstances.

**COUNT I**  
**Strict Products Liability--Defective Manufacturing**  
**As to Organon Defendants**

34. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.

35. Defendants Organon is the manufacturer, designer, distributor, seller, or supplier of NuvaRing and was responsible for marketing, labeling, and/or selling the NuvaRing and otherwise putting it into the stream of commerce.

36. The NuvaRing manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants Organon, was defective in its manufacture and construction when it left the hands of Defendants Organon in that it deviated from product specifications, rendering it unreasonably dangerous and thereby posing a serious risk of injury and death to consumers, including Plaintiff.

37. As a direct and proximate result of using Defendant Organon's unreasonably dangerous product, Plaintiff sustained injuries as described herein. As a result, Plaintiff suffers economic loss, non-economic loss, and damages for aggravating circumstances and other losses in an amount to be proven at trial.

38. As a direct and proximate result of the said wrongful, willful and reckless acts and conduct of the Defendants, Plaintiff suffered greatly and endured excruciating pain and suffering from the initial onset of her injuries until the time of her pulmonary embolism, incurring substantial medical and other expenses as a result.

**WHEREFORE**, Plaintiff demands Judgment on this Count against Defendants,

Individually, jointly, severally, or in the alternative, for compensatory damages, exemplary damages, attorney's fees, costs of suit and all such other and further relief as the Court deems just and proper.

## **COUNT II**

### **Strict Products Liability – Defective Design As to Organon Defendants**

39. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.

40. Defendants Organon are the manufacturer, designer, distributor, seller, or supplier of NuvaRing and was responsible for marketing, labeling, and/or selling the NuvaRing and otherwise putting it into the stream of commerce.

41. The NuvaRing manufactured and supplied by Defendants Organon contained an unreasonably dangerous defect in design or formulation in that, when it left the hands of Defendants Organon, an average consumer could not reasonably anticipate the dangerous nature of the NuvaRing nor fully appreciate the attendant risk of injury associated with using the NuvaRing.

42. NuvaRing was defective in that it was not properly designed or prepared and/or was not accompanied by proper warnings regarding the prevalence and severity of adverse side effects associated with its use.

43. NuvaRing was further defective in that its design and manufacture contained unnecessarily dangerous hormones and released uneven amount of the said hormones.

44. The foreseeable risks associated with the design of the NuvaRing include, but are not limited to, the fact that the NuvaRing is more dangerous and presents a greater risk of injury than an ordinary consumer would reasonably expect when using this type of product in an intended or reasonably foreseeable manner.

45. At the time the NuvaRing left the control of Defendants Organon, there were practical and feasible alternative designs that would have prevented and/or significantly reduced the risk of Plaintiff's injuries without impairing the reasonably anticipated or intended function of the product. These safer alternative designs were economically and technologically feasible, including use of a second generation progestin, and would have prevented or significantly reduced the risk of Plaintiffs injuries without substantially impairing the product's utility.

46. As a direct and proximate result of using Defendant Organon's unreasonably dangerous product, Plaintiff sustained injuries as described herein. As a result, Plaintiff suffers economic loss, non-economic loss, and damages for aggravating circumstances and other losses in an amount to be proven at trial.

47. As a direct and proximate result of the said wrongful, willful and reckless acts and conduct of the Defendants, Plaintiff suffered greatly and endured excruciating pain and suffering from her injuries, incurring substantial medical and other expenses as a result.

**WHEREFORE**, Plaintiff demands Judgment on this Count against Defendants, Individually, jointly, severally, or in the alternative, for compensatory damages, exemplary damages, attorney's fees, costs of suit and all such other and further relief as the Court deems just and proper.

### **COUNT III**

#### **Strict Products Liability -- Defect Due to Inadequate Warning As to Organon Defendants**

48. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.

49. The NuvaRing manufactured and supplied by Defendants Organon was unreasonably dangerous due to inadequate warning or instruction because Defendants Organon knew or should have known that the product created hidden risks of serious bodily harm and death and they failed to adequately warn Plaintiff and/or her health care providers of the extent of such risks, including the extent of risk of the types of injuries Plaintiff suffered as a result of using the NuvaRing.

50. Defendants marketed, promoted and advertised their NuvaRing product to physicians and to the public as more effective and safe than the oral contraceptive pill, at a time that the Defendants had actual and/or constructive knowledge that the NuvaRing was less safe than the pill.

51. Defendants failed to warn prescribing physicians and the public that the NuvaRing was associated with increased risk of cardiovascular thromboembolic complications than the pill.

52. Defendants knew, but failed to disclose that the NuvaRing had a higher risk of cardiovascular thromboembolic complications than the pill, due to the markedly potentiated androgenic effects caused by the synthetic progestin used in the NuvaRing.

53. Defendants failed to provide proper and full information as to the safety of the NuvaRing to the U.S. Food and Drug Administration, which regulates the sale of the NuvaRing.

54. Defendants did not reasonably warn the medical profession of precautions and known potential complications of NuvaRing to enable physicians and other healthcare providers to reasonably assess the risks versus the benefits of the use of the NuvaRing for contraception.

55. Defendants failed to adequately warn prescribing physicians, pharmacists, and users of the NuvaRing of the refrigerated storage requirements.

56. Plaintiff and her prescribing physician were unaware of the increased risks and danger of harm inherent in NuvaRing, as above described, and would have used and prescribed other methods for birth control if they had been so informed.

57. Defendants' failure to warn of the increased risks and danger of harm inherent in NuvaRing, as described above, created an unreasonable danger to users of this product, and the product was unreasonably dangerous at the time it was prescribed to Plaintiff.

58. Plaintiff was prescribed and used the NuvaRing for its intended purpose and as reasonably anticipated without knowledge of its characteristics, and could not have discovered any defect in the product through the exercise of reasonable care.

59. The warnings that were given by Organon were not accurate, clear and/or were ambiguous.

60. As a direct and proximate result of Defendant Organon's inadequate warnings regarding the safety of NuvaRing, Plaintiff sustained injuries as described

herein. As a result, Plaintiff suffers economic loss, non-economic loss, and damages for aggravating circumstances and other losses in an amount to be proven at trial.

61. As a direct and proximate result of the said wrongful, willful and reckless acts and conduct of the Defendants, Plaintiff suffered greatly and endured excruciating pain and suffering from her injuries, incurring substantial medical and other expenses as a result, for which Plaintiff is entitled to recover.

**WHEREFORE**, Plaintiff demands Judgment on this Count against Defendants, Individually, jointly, severally, or in the alternative, for compensatory damages, exemplary damages, attorney's fees, costs of suit and all such other and further relief as the Court deems just and proper.

**COUNT IV**  
**Breach of Express Warranty**  
**As to Organon Defendants**

62. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.

63. Defendants Organon expressly warranted that the NuvaRing was a safe and effective prescription contraceptive.

64. Defendants promoted NuvaRing to the FDA, prescribing doctors, the public and Plaintiff, as "safe," "favorable safety profile," "low side effects," "less side effects," "low hormones" and other similar terms.

65. Defendants deliberately promoted what it called "low estrogen" in its said product as a means of avoiding reference to the dangerous progestin which it used in the product, and used the dangerous progestin as compared to other, safer progestins to save money since they owned the patent to the progestin which they used.

66. Members of the consuming public, including the Plaintiff, were intended beneficiaries of the warranty.

67. The NuvaRing manufactured and sold by Defendants did not conform to these express representations because it caused serious injury to consumers when taken in recommended dosages.

68. Defendants breached their express warranty in one of more of the following ways:

- a) NuvaRing, as designed, innovated, marketed, manufactured, and/or sold and distributed by Defendants, was defectively designed and placed in to the stream of commerce by Defendants in a defective and unreasonably dangerous condition.
- b) Defendants failed to warn of the likelihood and severity of adverse side effects of NuvaRing, and/or did not provide adequate warnings and instructions on the product, nor did they employ other reasonable means to inform doctors and patients of the risks of the drug.
- c) Defendants failed to adequately test NuvaRing and to monitor its effects.
- d) Defendants failed to provide timely and adequate post-marketing warnings and instructions after they knew the true risks of injury from NuvaRing.

69. As a direct and proximate result of Defendants Organon's breach of warranty, Plaintiff sustained injuries as described herein. As a result, Plaintiff suffers economic loss, non-economic loss, and damages for aggravating circumstances and other losses in an amount to be proven at trial.

70. As a direct and proximate result of the said wrongful, willful and reckless acts and conduct of the Defendants, Plaintiff suffered greatly and endured excruciating

pain and suffering from her injuries, incurring substantial medical and other expenses as a result, for which Plaintiff is entitled to recover.

**WHEREFORE**, Plaintiff demands Judgment on this Count against Defendants, Individually, jointly, severally, or in the alternative, for compensatory damages, exemplary damages, attorney's fees, costs of suit and all such other and further relief as the Court deems just and proper.

**COUNT V**  
**Breach of Implied Warranty**  
**As to Organon Defendants**

71. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.

72. At the time Defendants Organon designed, manufactured, marketed, sold, and distributed NuvaRing for use by Plaintiff, Defendants knew of the use for which NuvaRing was intended and impliedly warranted the product to be of merchantable quality and safe for such use.

73. Plaintiff reasonably relied upon the skill and judgment of Defendants Organon as to whether NuvaRing was of merchantable quality and safe for its intended use and upon the Defendants Organon's implied warranty as to such matters.

74. Contrary to such implied warranty, NuvaRing was not of merchantable quality or safe for its intended use, because the product was unreasonably dangerous as described above.

75. As a direct and proximate result of Defendants Organon's breach of warranty, Plaintiff sustained fatal injuries as described herein. As a result, Plaintiff

suffers economic loss, non-economic loss, and damages for aggravating circumstances and other losses in an amount to be proven at trial.

76. As a direct and proximate result of the said wrongful, willful and reckless acts and conduct of the Defendants, Plaintiff suffered greatly and endured excruciating pain and suffering from her injuries, incurring substantial medical and other expenses as a result, for which Plaintiff is entitled to recover.

**WHEREFORE**, Plaintiff demands Judgment on this Count against Defendants, Individually, jointly, severally, or in the alternative, for compensatory damages, exemplary damages, attorney's fees, costs of suit and all such other and further relief as the Court deems just and proper.

## **COUNT VI**

### **Strict Products Liability Defect Due to Nonconformance with Representations As to Organon Defendants**

77. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.

78. Defendants Organon made representations regarding the safety of NuvaRing.

79. The representations that Defendants Organon made regarding the safety of NuvaRing were made on Defendant Organon's knowledge, or under circumstances in which Defendants Organon necessarily ought to have known the truth or untruth of the representations.

80. The NuvaRing supplied by Defendants Organon was defective in that it did not conform to representations made by Defendants concerning the safety of the product.

81. Defendants Organon had an economic interest in all transactions involving sales and prescriptions of NuvaRing.

82. Plaintiff justifiably relied upon all Defendant Organon's representations regarding the NuvaRing when she used it.

83. As a direct and proximate result of Defendants' misrepresentations regarding the safety of NuvaRing, Plaintiff sustained injuries as described herein. As a result, Plaintiff suffers harm, economic loss, non-economic loss, and damages for aggravating circumstances and other losses in an amount to be proven at trial.

84. As a direct and proximate result of the said wrongful, willful and reckless acts and conduct of the Defendants, Plaintiff suffered greatly and endured excruciating pain and suffering from her injuries, incurring substantial medical and other expenses as a result, for which Plaintiff is entitled to recover.

**WHEREFORE**, Plaintiff demands Judgment on this Count against Defendants, Individually, jointly, severally, or in the alternative, for compensatory damages, exemplary damages, attorney's fees, costs of suit and all such other and further relief as the Court deems just and proper.

## COUNT VII

### **Strict Products Liability Defect Due to Failure to Adequately Test As to Organon Defendants**

85. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.

86. Defendants Organon repeatedly advised consumers and the medical community that the NuvaRing contained the same safety profile as oral hormonal birth control pills. Defendants Organon failed to adequately test the safety of the NuvaRing versus oral hormonal birth control pills.

87. Had Defendants Organon adequately tested the safety of the NuvaRing versus oral hormonal birth control pills and disclosed those results to the medical community or the public, Plaintiff would not have undertaken birth control therapy with the NuvaRing.

88. As a direct and proximate result of Defendant Organon's failure to adequately test the safety of the NuvaRing versus oral hormonal birth control pills, Plaintiff sustained fatal injuries as described herein. As a result, Plaintiff suffers harm, economic loss, non-economic loss, and damages for aggravating circumstances and other losses in an amount to be proven at trial.

89. As a direct and proximate result of the said wrongful, willful and reckless acts and conduct of the Defendants, Plaintiff suffered greatly and endured excruciating pain and suffering from her, incurring substantial medical and other expenses as a result, for which Plaintiff is entitled to recover.

**WHEREFORE**, Plaintiff demands Judgment on this Count against Defendants,

Individually, jointly, severally, or in the alternative, for compensatory damages, exemplary damages, attorney's fees, costs of suit and all such other and further relief as the Court deems just and proper.

## **COUNT VIII**

### **Negligence As to Organon Defendants**

90. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.

91. Defendants Organon had a duty to exercise reasonable care in the design, manufacture, sale and/or distribution of NuvaRing into the stream of commerce, including a duty to assure that its product did not pose a significantly increased risk of bodily harm and adverse events.

92. Defendants Organon failed to exercise ordinary care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotions and distribution of NuvaRing into interstate commerce in that Defendants Organon knew, or should have known, that the product caused such significant bodily harm or death and was not safe for use by consumers.

93. Defendants Organon failed to exercise ordinary care in the labeling of NuvaRing and failed to issue to consumers and/or their health care provider's adequate warnings of the risk of serious bodily injury or death due to the use of the NuvaRing.

94. Despite the fact that Defendants Organon knew or should have known that NuvaRing posed a serious risk of bodily harm to consumers, Defendants Organon continued to manufacture and market NuvaRing for use by consumers.

95. Defendants Organon knew or should have known that consumers, including Plaintiff, would foreseeably suffer injury as a result of Defendant Organon's failure to exercise ordinary care as described above.

96. Defendants deliberately bypassed confining its promotion of NuvaRing to learned intermediaries and instead engaged in extensive and expensive direct-to-consumer advertising, including over the internet, in which promotional material adequate warnings were not given, thereby assumed a direct duty to the user.

97. Plaintiff's injuries and damages alleged herein were and are the direct and proximate result of the negligence of Defendants Organon as follows:

- a) In its failure to warn or instruct, and/or adequately warn or adequately instruct, users of the NuvaRing, including Plaintiff, of its known dangerous and defective characteristics;
- b) In its design, development, implementation, administration, supervision and/or monitoring of clinical trials for the NuvaRing;
- c) In its promotion of the NuvaRing in an overly aggressive, deceitful and fraudulent manner, despite knowledge of the product's defective and dangerous characteristics due to its propensity to cause serious injury and/or death;
- e) In representing that the NuvaRing was safe for its intended use when, in fact, the product was unsafe for its intended use;
- f) In utilizing dangerous levels of Progestin which was never used before as a starting agent in contraceptives and without first conducting adequate testing;

- g) In utilizing combined contraceptives in a vaginal route of administration without first conducting adequate testing as to the release and/or exposure rates of such contraceptives;
- h) In failing to perform appropriate pre-market testing of the NuvaRing;
- i) In failing to perform appropriate post-market testing of the NuvaRing;
- j) In failing to perform appropriate post-market surveillance of the NuvaRing;
- k) In failing to properly ship, transport, and deliver the NuvaRing in the required refrigerated storage;
- l) In failing to adequately instruct its employees and/or agents and medical professionals of the necessity to store the NuvaRing in refrigerated containers; and
- m) In failing to have uniform labels on contraindications of use of the product.

98. As a direct and proximate result of Defendant Organon's negligence, Plaintiff sustained injuries as described herein. As a result, Plaintiff suffers harm, economic loss, non-economic loss, and damages for aggravating circumstances and other losses in an amount to be proven at trial.

99. As a direct and proximate result of the said wrongful, willful and reckless acts and conduct of the Defendants, Plaintiff suffered greatly and endured excruciating pain and suffering from her injuries, incurring substantial medical and other expenses as a result, for which Plaintiff is entitled to recover.

**WHEREFORE**, Plaintiff demands Judgment on this Count against Defendants, Individually, jointly, severally, or in the alternative, for compensatory damages, exemplary damages, attorney's fees, costs of suit and all such other and further relief as the Court deems just and proper.

**COUNT IX**  
**Intentional and/or Negligent Misrepresentation**  
**As to Organon Defendants**

100. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.

101. Defendants Organon knew or was aware or should have been aware that the NuvaRing had not been sufficiently tested, and was unsafe, defective in design and manufacture, unreasonably dangerous and/or that it lacked adequate and/or sufficient warnings.

102. Defendants Organon knew and were aware or should have been aware that the NuvaRing promoted more risks of clotting than other contraceptives demonstrating that further testing was needed.

103. Defendants Organon knew or should have known that the NuvaRing had a potential to, could, and would cause severe and grievous injury to the users of said product, and that it was inherently dangerous in a manner that exceeded any purported, inaccurate, and/or down-played warnings.

104. Defendants Organon knew or should have known the safety profile in the US label was misleading to prescribing doctors and users of the NuvaRing, including the Plaintiff, as the label contained contraindications different than that of other NuvaRing labels.

105. Plaintiff reasonably relied upon Defendant Organon's representations to Plaintiff and/or her health care providers that NuvaRing was safe for human consumption and/or use and that Defendant Organon's labeling, advertisements and promotions fully described all known risks of the product.

106. As a direct and proximate result of Defendant Organon's fraudulent and/or negligent actions and omissions, Plaintiff used NuvaRing and sustained injuries as described herein. As a result, Plaintiff suffers harm, economic loss, non-economic loss, and damages for aggravating circumstances and other losses in an amount to be proven at trial.

107. As a direct and proximate result of the said wrongful, willful and reckless acts and conduct of the Defendants, Plaintiff suffered greatly and endured excruciating pain and suffering from her injuries, incurring substantial medical and other expenses as a result, for which Plaintiff is entitled to recover.

**WHEREFORE**, Plaintiff demands Judgment on this Count against Defendants, Individually, jointly, severally, or in the alternative, for compensatory damages, exemplary damages, attorney's fees, costs of suit and all such other and further relief as the Court deems just and proper.

**COUNT X**  
**Violation of the Missouri Merchandising Practices Act**  
**As to Organon Defendants**

108. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.

109. At all times relevant, the Missouri Merchandising Practices Act, VAMS §§ 407.010 et seq., (hereinafter "MPA") prohibited "[t]he act, use or employment by any

person of any deception, fraud, false pretense, false promise, misrepresentation, unfair practice or the concealment, suppression or omission of any material fact in connection with the sale or advertisement of any merchandise in trade or commerce" and declares such acts or practices as unlawful.

110. Defendants Organon violated the MPA by the use of false and misleading misrepresentations or omissions of material fact in connection with the marketing, promotion, and sale of the NuvaRing. Defendants communicated the purported benefits of the NuvaRing while failing to disclose the serious and dangerous side effects related to the use of the NuvaRing with the intent that consumers, like Plaintiff, and her healthcare providers would rely upon the misrepresentations and purchase or prescribe the NuvaRing.

111. As a result of violating the MPA, Defendants caused Plaintiff to be prescribed and to use NuvaRing, causing injuries as described herein. As a result, Plaintiff suffers harm, economic loss, non-economic loss, and damages for aggravating circumstances and other losses in an amount to be proven at trial.

112. As a direct and proximate result of the said wrongful, willful and reckless acts and conduct of the Defendants, Plaintiff suffered greatly and endured excruciating pain and suffering from her injuries, incurring substantial medical and other expenses as a result, for which Plaintiff is entitled to recover.

**WHEREFORE**, Plaintiff demands Judgment on this Count against Defendants, Individually, jointly, severally, or in the alternative, for compensatory damages, exemplary damages, attorney's fees, costs of suit and all such other and further relief as the Court deems just and proper.

## COUNT XI

### **Successor Liability As to Defendant Merck**

113. In or about November 2009, Defendant Merck, a New Jersey corporation organized, existing and conducting business in the State of New Jersey with its principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033 completed the acquisition and merger with Schering-Plough Corporation, which included Organon and the liabilities and assets associated with NuvaRing®.

114. Upon information and belief, Defendant Merck expressly and/or impliedly assumed the liabilities and obligations of Schering-Plough and the named Organon defendants for the injuries and damages alleged herein resulting from Plaintiff's use of NuvaRing®.

115. Upon information and belief, Defendant Merck has continued the business and operation of Schering-Plough and the named Organon Defendants, including, but not necessarily limited to the NuvaRing®.

116. Therefore, Defendant Merck is liable to Plaintiff for the injuries and damages alleged herein as a successor in interest and/or Successor Corporation of Schering-Plough and the Organon defendants named herein.

### **PRAYER FOR RELIEF**

**WHEREFORE**, for the foregoing reasons, Plaintiff prays for relief as follows:

1. Damages against all defendants in excess of \$75,000.00, and in an amount that is fair and just to compensate Plaintiff for the damages she has suffered and will

continue to suffer as a result of Plaintiff injuries including, without limitation, economic loss, non-economic loss, and all other damages.

2. Damages due to the aggravating circumstances attending Plaintiff injuries;
3. Damages against all defendants based on the intense pain and suffering that Plaintiff endured from the initial onset of her injuries and continued follow up appointments, and for the substantial medical and other expenses that she incurred as a result;
4. Attorneys' fees, expenses, and costs of this action; and
5. Such further relief as this Court deems necessary, just and proper.

**JURY DEMAND**

Plaintiff hereby demands a trial by jury.

Respectfully submitted,

**SCHLICHTER, BOGARD & DENTON**

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